



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

Marc J. Scheineson  
Alston & Bird LLP  
The Atlantic Building  
950 F Street, NW  
Washington, DC 20004-1404

JUN 02 2008

Received  
electronically  
8/11/08  
16:58  
JL/DM

Re: Advisory Opinion Request--Docket No. 2007A-0332

Dear Mr. Scheineson:

This letter responds to your letters to the Food and Drug Administration (FDA) dated August 24, 2007 and October 11, 2007 requesting an advisory opinion on: 1) whether all bovine thrombin products must contain the required hemostatic abnormality warning language in a box, or the use of such a box is limited to only a particular class of products; 2) whether Vascular Solutions' bovine thrombin products must bear such "boxed" warning; and 3) whether the required placement of the warning information, boxed or unboxed, is limited to instructions for use/package inserts, or whether this warning information must appear in all labeling and/or promotional/advertising materials for all bovine thrombin products.

A request for an advisory opinion may be denied under 21 C.F.R. 10.85(a)(2) when, among other circumstances, "the request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability." The issues you address are particular in nature and do not raise a policy issue of broad applicability.

As you may know, the agency promulgated a proposed rule (57 FR 47314; October 15, 1992) to amend 21 CFR 10.85 based on concerns related to the legal sufficiency of certain provisions contained in this regulation. Specifically, § 10.85(e) states that an advisory opinion obligates the agency to follow it until it is amended or revoked, and states that the Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion. However, as noted in the proposed rule, courts have been reluctant to follow § 10.85 on grounds that the agency cannot be estopped from enforcing the act (57 FR at 47315). This proposed rule has not been finalized.

Since the publication of the proposed rule to amend § 10.85, Congress amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 701(h)) to require FDA to establish guidance documents with public participation. The agency's regulations in 21 CFR 10.115, implementing this statutory provision, provide a process by which the agency can set forth its interpretation of, or policy on, a regulatory issue to applicants/sponsors and the public (21 CFR 10.115(b)(1)).

For the above reasons, we are denying your request for an advisory opinion. However, based on your request, FDA plans to consider the need to provide clarity for the labeling of

FDA-2007-A-0163

PDN

Page 2- Mr. Marc J. Scheineson

bovine-thrombin-based hemostatic products through guidance or another process the agency may deem appropriate.

If you have any questions, please contact Paul Gadiock of the Center for Devices and Radiological Health Regulations Staff at (240) 276-2343.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Jeffrey Shuren', with a horizontal line extending to the right.

Jeffrey Shuren  
Associate Commissioner  
for Policy and Planning